

The invention in which an exclusive right is claimed is defined by the following:

1. A method for closing a puncture in a vascular vessel of a patient, comprising the steps of:

- (a) determining a site of the puncture in the vascular vessel;
- (b) positioning an ultrasonic transducer applicator at a position adjacent to the site that was determined;
- (c) coupling the ultrasonic transducer applicator to a control that includes a processor programmed to control administration of ultrasonic energy to efficaciously seal a puncture; and
- (d) enabling a user to initiate a process that is controlled by the control, said control automatically controlling the ultrasonic transducer applicator so that the ultrasonic energy produced by the ultrasonic transducer applicator is focused at the site and is administered to the site at a sufficient intensity and duration to denature tissue at the puncture, closing and sealing the puncture.

2. The method of Claim 1, wherein the step of determining the site of the puncture comprises the steps of:

- (a) generating an imaging ultrasonic beam with the ultrasonic transducer applicator, said imaging ultrasonic beam being transmitted into the patient proximate an expected location for the site;
- (b) receiving a reflection of the imaging ultrasonic beam from within the patient with the ultrasonic transducer applicator, producing a corresponding output signal; and
- (c) processing the output signal with the processor in the control, to determine the site of the puncture.

3. The method of Claim 2, further comprising the step of providing a visual indication of a location of the site of the puncture, thereby enabling an operator to position the ultrasonic transducer applicator so that the ultrasonic energy produced by the ultrasonic transducer applicator is directed at the site of the puncture.

4. The method of Claim 3, wherein the visual indication comprises an image of the site in which an axis of the vascular vessel is visually evident, and wherein the step of enabling the operator further comprises the step of positioning the ultrasonic transducer applicator longitudinally along the axis of the vascular vessel so that the ultrasonic energy produced by the ultrasonic transducer applicator is directed at the site of the puncture.

5. The method of Claim 4, further comprising the step of providing an object that extends from outside the patient into the puncture.

6. The method of Claim 5, wherein the step of positioning includes the step of estimating the location of the puncture along the longitudinal axis of the vessel based upon a disposition of the object extending outside the patient.

7. The method of Claim 5, wherein the visual indication comprises an image of the site in which the object extending into the puncture is evident, further comprising the step of estimating the location of the puncture based upon a disposition of the object in the image.

8. The method of Claim 3, further comprising the steps of:

(a) processing the output signal with the processor to determine the site of the puncture;

(b) controlling an indicator disposed on the ultrasonic transducer applicator to provide an indication of a direction in which the ultrasonic transducer applicator should be moved to be adjacent to the site of the puncture.

9. The method of Claim 3, further comprising the step of using the processor for automatically controlling at least one of a direction, the intensity, and a focus of the ultrasonic energy, to ensure that the ultrasonic energy is administered to the site of the puncture.

10. The method of Claim 9, wherein the processor directs the ultrasonic energy so as to overscan the site of the puncture, ensure that the puncture is closed and sealed.

11. The method of Claim 10, wherein the processor moves the focus of the ultrasonic energy while administering the ultrasonic energy, to overscan the site of the puncture.

12. The method of Claim 1, wherein an ultrasound emitter of the ultrasonic transducer applicator has an aspheric shape so that the ultrasonic energy that is directed at the site of the puncture overscans the site, thereby ensuring the ultrasonic energy is applied to the site of the puncture.

13. The method of Claim 2, wherein the ultrasonic transducer applicator uses a common array of transducers for generating both the imaging ultrasound beam and the ultrasound energy that closes and seals the puncture.

14. The method of Claim 2, further comprising the step of interrupting the administration of the ultrasonic energy to again generate the imaging ultrasound beam, thereby confirming whether the ultrasonic energy is being directed at the site of the puncture.

15. The method of Claim 1, further comprising the step of employing the processor to control a force applied against a surface of the patient with a force generator included in the ultrasonic transducer applicator, said force being controlled so that a pressure developed by said force is sufficient to substantially stop fluid leakage from the vascular vessel, but not so great as to substantially occlude fluid flow through the vascular vessel.

16. The method of Claim 1, further comprising the step of enclosing a ultrasonic transducer within a protective shell to provide the ultrasonic transducer applicator, said protective shell being adapted to contact an external dermal portion of the patient in order to convey the ultrasonic energy transdermally to the site of the puncture and protecting against a direct contact between the ultrasonic transducer and the external dermal portion of the patient.

17. A method for closing a puncture in a vascular vessel of a patient, comprising the steps of:

- (a) determining a site of the puncture in the vascular vessel;
- (b) providing a protective applicator shell for an ultrasonic transducer;
- (c) mating the ultrasonic transducer with the protective applicator shell to provide an ultrasonic transducer applicator;
- (d) positioning the ultrasonic transducer applicator externally on the patient, adjacent to the site determined for the puncture in the vascular vessel;
- (e) energizing the ultrasonic transducer applicator to administer ultrasonic energy to the puncture in the vascular system, said ultrasonic energy denaturing tissue at the puncture, closing and sealing the puncture.

18. The method of Claim 17, further comprising the step of removing a cover overlying a gel disposed on a face of the protective applicator shell prior to the step of positioning the ultrasonic transducer, said gel providing an ultrasonic coupling interface between the ultrasonic transducer and a dermal surface of the patient through which the ultrasonic energy is conveyed.

19. The method of Claim 17, wherein the step of determining the site of the puncture comprises the steps of:

(a) generating an imaging ultrasonic beam with the ultrasonic transducer applicator, said imaging ultrasonic beam being transmitted into the patient proximate an expected location for the site;

(b) receiving a reflection of the imaging ultrasonic beam from within the patient with the ultrasonic transducer applicator, producing a corresponding output signal; and

(c) using the output signal to determine the site of the puncture.

20. The method of Claim 19, further comprising the step of providing a visual indication of a location of the site of the puncture, thereby enabling an operator to position the ultrasonic transducer applicator so that the ultrasonic energy produced by the ultrasonic transducer applicator is directed at the site of the puncture.

21. The method of Claim 20, wherein the visual indication comprises an image of the site in which an axis of the vascular vessel is visually evident, and wherein the step of enabling the operator further comprises the step of positioning the ultrasonic transducer applicator longitudinally along the axis of the vascular vessel so that the ultrasonic energy produced by the ultrasonic transducer applicator is directed at the site of the puncture.

22. The method of Claim 21, further comprising the step of providing an object that extends from outside the patient into the puncture.

23. The method of Claim 22, wherein the step of positioning includes the step of estimating the location of the puncture along the longitudinal axis of the vessel based upon a disposition of the object extending outside the patient.

24. The method of Claim 22, wherein the visual indication comprises an image of the site in which the object extending into the puncture is evident, further comprising the step of estimating the location of the puncture based upon a disposition of the object in the image.

25. The method of Claim 17, further comprising the step of overscanning the site of the puncture with the ultrasonic energy to ensure that the ultrasonic energy is administered to the seal the puncture.

26. The method of Claim 19, wherein the ultrasonic transducer applicator uses a common array of transducers for generating both the imaging ultrasound beam and the ultrasound energy that closes and seals the puncture.

27. The method of Claim 19, further comprising the step of interrupting the administration of the ultrasonic energy when sealing the puncture to again generate the imaging ultrasound beam, thereby confirming whether the ultrasonic energy is being directed at the site of the puncture.

28. The method of Claim 17, further comprising the step of activating a force generator included within the ultrasonic transducer applicator to produce a pressure applied against a dermal layer of the patient over the site of the puncture.

29. The method of Claim 28, further comprising the step of providing an indication that the pressure being applied to the site of the puncture is sufficient to substantially prevent a fluid from leaking from the vascular vessel, but not so great as to substantially occlude a fluid flow through the vascular vessel.

30. Apparatus adapted to seal a puncture in a vascular vessel of a patient, comprising:

(a) an ultrasonic transducer applicator that controllably radiates ultrasonic energy and which is adapted to:

(i) couple the ultrasonic energy into a body of a patient;

(ii) controllably focus the ultrasonic energy on a puncture disposed in a vascular vessel of a patient; and

(iii) administer the ultrasonic energy to the site at an intensity sufficient to denature tissue, closing and sealing the puncture; and

(b) a controller that is coupled to the ultrasonic transducer applicator, said controller including a processor and a memory in which are stored

machine instructions, said machine instructions, when executed by the processor, causing it to control a plurality of parameters affecting administration of the ultrasonic energy to the site by the ultrasonic transducer applicator, said parameters being controlled by the processor so as to efficaciously close and seal a puncture in a vascular system of a patient.

31. The apparatus of Claim 30, further comprising a display coupled to the controller, said ultrasonic transducer applicator being controlled by the controller to produce an imaging ultrasonic beam adapted to be transmitted into a patient proximate an expected location for the site of the puncture, said ultrasonic transducer applicator producing an output signal in response to receiving a reflection of the imaging ultrasonic beam, said output signal being used to provide an image on the display useful for determining the site of a puncture.

32. The apparatus of Claim 31, further comprising an object that is adapted to be introduced into a puncture and to extend externally, said object providing a visual indication of a location of a site of a puncture.

33. The apparatus of Claim 32, wherein the object is at least in part formed of a material that is clearly visually evident on the display, to assist in determining a site of a puncture.

34. The apparatus of Claim 33, wherein a portion of the object adapted to be disposed at a puncture comprises a material that is more visually evident on the display than other portions of the object, to assist in determining a site of a puncture.

35. The apparatus of Claim 30, wherein the ultrasonic transducer applicator includes an indicator that is coupled to the controller, said controller responding to the output signal to provide a visual indication with the indicator, said visual indication denoting a direction in which the ultrasonic transducer applicator should be moved to enable the ultrasonic energy to be more accurately directed at a puncture site.

36. The apparatus of Claim 30, wherein the processor automatically controls at least one of a direction, an intensity, and a focus of the ultrasonic energy, to ensure that the ultrasonic energy is administered to a site of a puncture.

37. The apparatus of Claim 36, wherein the machine instructions executed by the processor control the ultrasonic transducer applicator to direct the ultrasonic energy so as to overscan a site of a puncture, to ensure that a puncture is closed and sealed thereby.

38. The apparatus of Claim 36, wherein the machine instructions executed by the processor control the ultrasonic transducer applicator to shift a focus of the ultrasonic energy to overscan a site of a puncture.

39. The apparatus of Claim 30, wherein the ultrasonic transducer applicator includes an emitter face having an aspheric shape so that the ultrasonic energy emitted thereby is focused to encompass an area substantially greater than a site of a puncture, to ensure that the ultrasonic energy is applied to a puncture.

40. The apparatus of Claim 31, wherein the ultrasonic transducer applicator includes an ultrasound emitter that is controlled by the processor in accord with the machine instructions to emit both the ultrasound energy employed to close and seal a puncture and the imaging ultrasound beam that is used to determine a site of a puncture.

41. The apparatus of Claim 31, wherein the machine instructions executed by the processor further cause the processor to interrupt administration of the ultrasonic energy to a site of a puncture to generate the imaging ultrasonic beam, for again displaying an image to confirm whether the ultrasonic energy is being accurately directed to a site of a puncture.

42. The apparatus of Claim 30, wherein the ultrasonic transducer applicator further comprises a force generator that produces a pressure controlled by the processor in accord with the machine instructions executed by the processor.

43. The apparatus of Claim 42, further comprising a force sensor that monitors a force being applied against a surface of a patient, producing a signal indicative thereof that is coupled to the control, said control employing the signal to vary a pressure caused by the force generator so that the pressure is sufficient to substantially prevent a fluid leaking from a puncture, but not so great as to substantially occlude a fluid flow through a vascular vessel in which a puncture is disposed.

44. The apparatus of Claim 30, wherein the ultrasonic transducer applicator comprises an ultrasonic emitter face and a protective shell adapted to contact an external dermal portion of a patient in order to convey the ultrasonic energy transdermally to a site of a puncture, while protecting against the ultrasonic emitter face directly contacting an external dermal portion of a patient.

45. Apparatus adapted to seal a puncture in a vascular vessel of a patient, comprising:

(a) an ultrasonic transducer that controllably radiates ultrasonic energy and which is adapted to:

(i) controllably focus the ultrasonic energy on a site where a puncture is disposed in a vascular system of a patient; and

(ii) generate ultrasonic energy at an intensity sufficient to denature tissue, closing and sealing a puncture; and

(b) a protective applicator shell sized to fit over the ultrasonic transducer and including a facing surface adapted to contact an external surface of a patient's body at the site where a transdermal puncture extends into a vascular vessel of a patient, said protective applicator shell coupling the ultrasonic generated by the ultrasonic transducer into a patient's body at the site and protecting against the ultrasonic transducer directly contacting a patient while a puncture is being closed and sealed by the ultrasonic energy.

46. The apparatus of Claim 45, wherein the protective applicator shell includes an outer surface on which is disposed a patch of a gel covered by a removable tab, said patch of the gel being exposed upon removal of the tab to facilitate coupling of the ultrasound energy into a body of a patient.

47. The apparatus of Claim 45, wherein the protective applicator shell includes an interior cavity into which the ultrasonic transducer is inserted, said cavity including a layer of a gel to facilitate coupling of the ultrasonic energy produced by the ultrasonic transducer into a surface with which the protective applicator shell is in contact.

48. The apparatus of Claim 45, wherein the ultrasonic transducer includes a cable, said protective applicator shell being provided for use in a sterile state and including a protective sheath that is adapted to prevent the cable from contacting a sterile field on a body of patient against which the protective applicator shell is brought into contact to administer the ultrasonic energy.



49. The apparatus of Claim 45, wherein the ultrasonic transducer is adapted to selectively generate a broad imaging beam and a focused beam for administering the ultrasonic energy to a puncture site, said broad imaging beam being used to determine a location of a site of a puncture in a vascular vessel.

50. The apparatus of Claim 45, wherein the protective applicator shell is substantially optically transparent to enable markings and indicators included on the ultrasonic transducer to be observed by an operator using the ultrasonic transducer while the ultrasonic transducer is fitted inside the protective applicator shell.